REMARKS

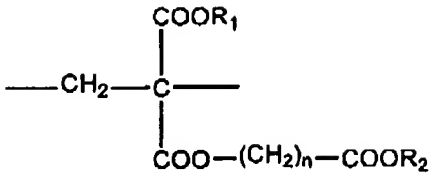
The Applicants appreciate the Examiner's thorough examination of the subject application. Applicants request reconsideration of the subject application based on the following remarks.

Claims 1-20, 37-42, and 52-53 are currently pending in the application, of which claims 12 and 13, have been withdrawn from consideration. Claims 1 and 37 have been amended, and new claim 53 has been added. Claims 21-36 have been cancelled in this or a previous amendment without prejudice or disclaimer to Applicants right to pursue the subject matter of the cancelled claims in this or a subsequent application. Support for the amendments to the claims can be found in the specification. No new matter has been added by the amendments to the specification or the claims.

As the office action is understood, the claim objections under Rule 1.75(c), claim rejections under 35 U.S.C. §112, second paragraph, and claim rejections under 35 U.S.C. §102(e) presented in the office action dated November 5, 2003 have been withdrawn. The sole remaining grounds for rejection of the claims is presented in paragraphs 4 and 5 of the final office action dated June 15, 2004.

Thus, Claims 1-11, 14-27, and 35-52 were rejected under 35 U.S.C. §103(a) as being allegedly unpatentable over Bru-Magniez et al. (U.S. Patent 6,211, 273). The rejection is traversed.

Claim 1, as amended, provides pharmaceutical compositions comprising microparticles having a mean particle size of between 1.0 μm and about 100 μm, wherein the microparticle comprises a polymeric support material in which a substance can be dispersed, wherein the support material comprises at least about 50% w/w of at least one homopolymer with a repeat unit according to Formula (I):



wherein

R_1 represents a C_1-C_6 alkyl group or a group $(CH_2)_m$-$COOR_3$ wherein m is an integer from 1 to 5 and R_3 is a C_1-C_6 alkyl group, R_1 and R_3 being the same or different;

R_2 represents a C_1-C_6 alkyl group the same or different from R_1 and R_3;

n is an integer from 1 to 5; and

at least one therapeutic agent that is encapsulated or dispersed in the polymeric support material of the microparticle.

Claim 37, as amended, provides methods of treating a urological disease or disorder comprising:

administering intravesically a microparticle having a mean particle size of between about 1.0 μm and 100 μm with one or more encapsulated therapeutic agents to the lumen of the bladder;

contacting the particles to the surface of the mucosa,

releasing the encapsulated therapeutic agent in a controlled manner to treat the urological disease or disorder.

In contrast, Bru-Magniez teaches methods of making nanoparticles having a particle size of less than 500 nm, which nanoparticles are composed of a therapeutic agent and a methylidene malonate polymer.

As the Bru-Magniez patent is understood, nanoparticles having a mean particle size of greater than 500 nm are neither disclosed nor suggested. Moreover, methods of preparing particles having a mean particle size of greater than 500 nm are neither disclosed nor suggested by Bru-Magniez. Thus, one skilled in the art would not have been motivated to prepare larger

particles including the 1.0-100 μm microparticles of the invention based on the Bru-Magniez disclosure.

The Bru-Magniez patent does not teach or suggest the use of any nanoparticle for the treatment of a urological disease or disorder. Moreover, Bru-Magniez does not teach or suggest any method of treatment comprising delivery of a particulate material to the bladder or more particularly, methods of treating urological diseases or disorders (including cancer) in which microparticles having a mean particle size of between 1.0 and 100μm are administered to the lumen of a patient's bladder.

Thus, one of ordinary skill in the art would not have been motivated to practice the instant invention based on the teachings or suggestions of the Bru-Magniez patent.

Applicants respectfully submit that claims 1 and 37 are patentable over the Bru-Magniez patent. Claims 2-20, 38-42, and 52-53 depend from claim 1 or claim 37 and are therefore also patentable over Bru-Magniez.

Early consideration and allowance of the application are earnestly solicited.

Respectfully submitted,

September 15, 2004

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September 15, 2004

Ms. Cheryl D. Rexroad
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Re: U.S. Application No. 09/972,565
POLYMER CONTROLLED DELIVERY OF A THERAPEUTIC AGENT
Your Reference No. DM-3766
Our Reference No. 55322 (71699)

Dear Cheryl:

Enclosed please find a copy of the Amendment Response as filed today with the United States Patent and Trademark Office in connection with the above-referenced application.

Please do not hesitate to contact us should you have any questions, or if we can be of any further assistance at this time.

Best regards,

John B. Alexander, Ph.D.
Patent Agent

JBA:mpc
Enclosure

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